

Applicant : Gary K. Schwartz
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Amendments To The Drawings

Attached herein are replacement sheets for Figures 4, 6 and 7 which are designated by the legend "Prior Art".

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REMARKS

Claim Status

Claims 31-38, 41 and 42 were pending in the application. Claim 36 has been amended.

New claims 43-50 have been added. Claim 43 is drawn to a method of treating cancer in a subject comprising administering to the subject a composition comprising an effective amount of aqueous coptis chinesis extract and a therapeutic agent. Support for claim 43 can be found, *inter alia*, on page 16, lines 4-7, and page 32, line 30 to page 33, line 13. Hence, Applicant submits that no new matter has been added.

Accordingly, upon entry of this amendment, claims 31-38, 41-50 are pending in the application.

Drawings

The Examiner indicated that Figures 4, 6 and 7 should be designated by a legend such as "Prior Art". Attached herein are replacement sheets for Figures 4, 6 and 7 which are designated by the legend "Prior Art".

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 36-38 and 42 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner rejected claim 36 for reciting "the treating of the coptis chinesis extract and the therapeutic agent is performed in a sequential manner".

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Claim 36 has been amended to recite "the coptis chinesis extract and the therapeutic agent are administered in a sequential manner". Applicant submits that claim 36 has been amended to obviate the rejection. Accordingly, Applicant respectfully requests that the rejection of claims 36-38 and 42 under 35 U.S.C. §112, second paragraph, be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 31 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Li et al. (2000). The rejection is respectfully traversed.

Li et al. teach Huanglian, a Chinese herbal extract, inhibited tumor growth and colony formation of gastric, colon, and breast cancer cell lines in a time- and dose-dependent manner *in vitro*. In contrast, claim 31 is drawn to a method for treating cancer in a subject comprising administering to the subject a composition consisting essentially of an effective amount of aqueous coptis chinesis extract.

The Examiner contends that Li et al. teach a method of inhibiting cancer cell growth by administering an effective amount of aqueous chinesis extract. The Examiner also contends that Li et al. teach 100% tumor growth inhibition can only be achieved using the whole herbal extract. Accordingly, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the method of Li et al. for inhibiting cell growth in human cancer cells by administering an effective amount of aqueous chinesis extract as a treatment of a solid tumor in a subject because the herbal

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extract was shown to inhibit cancer cell growth in vitro. The Examiner contends that there would have been a reasonable expectation of success in adapting the method of Li et al. to treat cancer in a subject. Applicant respectfully traverses.

As it is pointed out in the attached Declaration, Exhibit A, the in vitro data of Li et al. do not provide one of ordinary skill in the art a reasonable expectation of success in using aqueous chinesis extract to treat cancer in a subject because whether a drug or composition will be useful in clinic can only be determined by vigorous clinical trials. In vitro data bear no correlation to the success or failure in clinical uses. Li et al. only provide in vitro data. In contrast, the present specification provides data from clinical trials that indicate aqueous chinesis extract would be useful in treating cancer in a subject (see e.g. page 30, lines 1-7; page 31, lines 29-34; and page 34, lines 5-23).

In view of the above remarks, Applicant submits that Li et al. do not render the present invention obvious. Accordingly, Applicant respectfully requests that the rejection of claims 31 and 32 under 35 U.S.C. §103(a) be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 31-33, 35-38, 41 and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (2000) in view of Lin et al. (1999).

Li et al. has been discussed above. The Examiner contends that Lin et al. teach administering berberine and Paclitaxel to human

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cancer cells, wherein berberine is a major constituent of coptis chinesis and is used to inhibit tumor cell growth.

Applicant submits that the Examiner's description of the teaching of Lin et al. is incorrect. In contrary to the Examiner's assertion, Lin et al. teach cancer cells treated with berberine and Paclitaxel had increased cell viability as compared to cells treated with Paclitaxel alone (see Abstract of Lin et al.) Pretreatment with berberine prior to Paclitaxel also blocked Paclitaxel-induced cell cycle response and morphological changes. Therefore, "these results together suggest that berberine ... leads to reduced response to Paclitaxel in digestive track cancer cells." *Id.* Hence, instead of teaching the use of both berberine and Paclitaxel, Lin et al. actually teach away from the present invention by showing berberine diminished anti-tumor responses induced by Paclitaxel.

In view of the teaching of Li et al. and Lin et al., one of ordinary skill in the art would not reasonably conclude that it is desirable to treat cancer cells with both berberine (or coptis chinesis extract) and a therapeutic agent such as Paclitaxel. The combination of Li et al. and Lin et al. does not render the present invention obvious. Accordingly, Applicant respectfully requests that the rejection of claims 31-33, 35-38, 41 and 42 under 35 U.S.C. 103(a) be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 34 was rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (2000) and Lin et al. (1999), and further in view of Schwartz et al. (U.S. Patent 5,821,072).

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Claim 34 is drawn to a method of using a composition comprising (i) aqueous coptis chinesis extract, (ii) a therapeutic agent, and (iii) a protein kinase C inhibitor to treat cancer. Li et al. and Lin et al. have been discussed above. The Examiner contends that Schwartz et al. teach using an anti-tumor agent and a protein kinase C inhibitor to treat cancer.

As discussed above, Lin et al. actually teach a result opposite to that of the present invention, namely berberine diminished rather than enhanced anti-tumor responses induced by a therapeutic agent such as Paclitaxel. Hence, the combination of Li et al., Lin et al. and Schwartz et al. could not reasonably lead one of ordinary skill in the art to the present invention of using aqueous coptis chinesis extract together with a therapeutic agent to treat cancer. Accordingly, Applicant respectfully requests that the rejection of claim 34 under 35 U.S.C. 103(a) be withdrawn.

Conclusion

Applicants respectively maintain that all the grounds of rejections raised in the September 26, 2006 Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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